

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of: )  
 )  
 Joel S. Douglas, et al. ) Before the Examiner  
 )  
 New CON Application ) Unassigned  
 )  
 Filed July 3, 2003 ) Group Art Unit 3736  
 )  
**METHODS AND APPARATUS** ) July 3, 2003  
**FOR SAMPLING AND** )  
**ANALYZING BODY FLUID** )

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July 3, 2003

(Date of Deposit)

Charles P. Schmal

Name of Registered Representative

Signature

July 3, 2003

Date of Signature

**INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicant requests consideration of the references listed on attached form PTO-1449 and/or the additional information identified below in paragraph 3. A legible copy of each reference listed on form PTO-1449 is enclosed, except a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial Nos. 09/887,574; 09/552,243; 09/298,386; and 08/858,042.

1a. [X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application (other than a continued prosecution application), or

before the mailing date of the first Office Action on the merits,

**and thus no certification and/or fee is required.**

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ a fee of \$\_\_\_\_\_ (set forth in 37 CFR §1.17(p)) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**a fee of \$\_\_\_\_\_ (set forth in 37 CFR §1.17(p)) is enclosed.**

2. It is hereby certified

a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or

b. ☐ that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

c. ☐ A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.

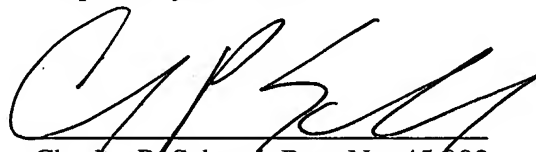
3. ☐ Consideration of the following additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ an English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☐ an English language translation of a foreign patent office search report submitted herewith,
  - d. ☐ the concise explanation contained in the specification of the present application at page<sup>s</sup> \_\_\_\_\_,
  - e. ☐ the concise explanation set forth in the attached English language abstract,
  - f. ☐ a copy of a related patent publication (in the English language) submitted herewith,
  - g. ☐ the concise explanation set forth below:

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b).

It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully Submitted,



Charles P. Schmal, Reg. No. 45,082  
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| Substitute for form 1449A/PTO<br><br><b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |                          |  |                                | <b>Complete if Known</b>                             |  |
|--|--------------------------|--|--------------------------------|--|--|
|  |                          |  |                                | Application Number                                   |  |
|  |                          |  |                                | Filing Date  | 7/3/2003   |
|  |                          |  |                                | First Named Inventor                                 | DOUGLAS  |
|  |                          |  |                                | Group Art Unit                                       | 3736   |
|  |                          |  |                                | Examiner Name  | Not Assigned   |
| Sheet  | 1                        | of   | 6                              | Attorney Docket Number                               | 7404-543   |
| <b>U.S. PATENT DOCUMENTS</b>   |                          |  |                                |  |  |
| Examiner<br>Initials*  | Cite<br>No. <sup>1</sup> | Document Number<br>Number-Kind Code (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Application of Cited Document | Pages, Columns, Lines where<br>Relevant Passages or Relevant<br>Figures Appear |
|  |                          | 3,623,475                                      | 11-30-1971                     | Sanz   |  |
|  |                          | 3,685,509                                      | 08-22-1972                     | Bentall  |  |
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|  |                          | 4,920,977                                      | 05-01-1990                     | Haynes   |  |

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|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
|-----------------------|--|--------------------|--|

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|   |                       |   |                                | Examiner Name  | Not Assigned   |
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|  |                          | Examiner Name   |                                | Not Assigned   |  |          |
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|  |                          | 5,320,607   | 06-14-1994                     | Ishibashi  |  |          |
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|   |                          |   |                                | Group Art Unit                                       | 3736   |
|   |                          |   |                                | Examiner Name  | Not Assigned   |
| Sheet   | 4                        | of  | 6                              | Attorney Docket Number                               | 7404-543   |
| <b>U.S. PATENT DOCUMENTS</b>  |                          |   |                                |  |  |
| Examiner<br>Initials*   | Cite<br>No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Application of Cited Document | Pages, Columns, Lines where<br>Relevant Passages or Relevant<br>Figures Appear |
|   |                          | D 254,444   | 03-11-1980                     | Levine   |  |

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| <b>FOREIGN PATENT DOCUMENTS</b>   |                          |                           |  |                                |   |  |                          |
| Examiner<br>Initials*   | Cite <sup>1</sup><br>No. | Foreign Patent Document   |  | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Application of Cited<br>Document | Pages, Columns, Lines where<br>Relevant Passages or Relevant<br>Figures Appear | T <sup>6</sup>           |
|   |                          | Country Code <sup>2</sup> | Number <sup>3</sup> -Kind Code <sup>5</sup> (if known) |                                |   |  |                          |
|   |                          | DE                        | 3,508,365  | 08-29-1985                     |   |  | <input type="checkbox"/> |
|   |                          | DE                        | 34 26 090  | 04-18-1985                     |   |  | <input type="checkbox"/> |
|   |                          | DE                        | 37 08 031  | 11-12-1987                     |   |  | <input type="checkbox"/> |
|   |                          | EP                        | 0 453 283  | 10-23-1991                     |   |  | <input type="checkbox"/> |
|   |                          | JP                        | 08000598   | 01-09-1996                     |   |  | <input type="checkbox"/> |
|   |                          | WO                        | 85/04089   | 09-26-1985                     |   |  | <input type="checkbox"/> |
|   |                          | WO                        | 88/00812   | 02-11-1988                     |   |  | <input type="checkbox"/> |
|   |                          | WO                        | 95/10223   | 04-20-1995                     |   |  | <input type="checkbox"/> |
|   |                          | WO                        | 97/43962   | 11-27-1997                     |   |  | <input type="checkbox"/> |

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| <b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>  |                       |  |   |                          |              |                          |
| <b>Examiner<br/>Initials*</b>   | <b>Cite<br/>No. 1</b> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published |   |                          |              | <b>T<sup>2</sup></b>     |
|   |                       | Critical Reviews in Bioengineering, 1990   |   |                          |              | <input type="checkbox"/> |
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|   |                       | ASH ET AL., "Subcutaneous Capillary Filtrate Collector for Measurement of Blood Glucose", ASAIO Journal, 1992  |   |                          |              | <input type="checkbox"/> |
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|   |                       | BRACE ET AL., "Re-evaluation of the Needle Method for Measuring Interstitial Fluid Pressure", American Journal of Physiology, 1975   |   |                          |              | <input type="checkbox"/> |
|   |                       | GINSBERG, "An Overview of Minimally Invasive Technologie", Clinical Chemistry, 1992  |   |                          |              | <input type="checkbox"/> |
|   |                       | JANLE-SWAIN ET AL., "Use of a Capillary Filtrate Collector for Monitoring Glucose in Diabetics", ASAIO Journal, 1987   |   |                          |              | <input type="checkbox"/> |
|   |                       | KAYASHIMA ET AL., "Suction Effusion Fluid from Skin and Constituent Analysis: New Candidate for Interstitial Fluid", American Journal of Physiology, 1992  |   |                          |              | <input type="checkbox"/> |
|   |                       | KORTHIUS ET LA., "Interstitium & Lymphatic Techniques",  |   |                          |              | <input type="checkbox"/> |
|   |                       | TURNER ET AL., "Diabetes Mellitus: Biosensors for Research and Management", Biosensors, 1985   |   |                          |              | <input type="checkbox"/> |

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| <b>Examiner<br/>Signature</b> |  | <b>Date<br/>Considered</b> |  |
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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